agency procedure, the change will be made without reviewing comments.

Statutory Authority: Section 814 of the Native American Programs Act of 1974, as amended.

Elizabeth Leo,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2020–02319 Filed 2–5–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0118]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our regulations requiring that the Agency receive prior notice before food is imported or offered for import into the United States.

DATES: Submit either electronic or written comments on the collection of information by April 6, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0118 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.'' Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain specific information that indicates prior refusals by any country and identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers.

This information collection enables FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *http://www.access.fda.gov/*. Information the Agency collects in the prior notice submission includes: (1) The submitter and transmitter (if different from the submitter); (2) entry type and CBP identifier; (3) the article of food, including complete FDA product code; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper, except for food imported by international mail; (9) the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, except for food imported by international mail; and (13) planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACS in column 6 entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under § 801(l) of the FD&C Act, § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions: Through ABI/ACS						
1.280 through 1.281	N/A	1,700	7,647	12,999,900	0.167 (10 minutes)	[2] 2,170,983
Through PNSI						
1.280 through 1.281	3540 [3]	27,000	70	1,890,000	0.384 (23 minutes)	725,760
Subtotal						2,896,743
Cancellations: Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1,760
Through PNSI						
1.282 and 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Subtotal						10,562
Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j)	N/A	1	1	1	8	8
1.285(i)	N/A	263	1	263	1	263
Subtotal						271
Total				14,932,412		2,907,576

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double-counting, an estimated 396,416 burden hours already accounted for in the Importer's Entry Notice information collection approved under OMB control number 0910–0046 are not included in this total.
[3] The term ''Form FDA 3540'' refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we have made no adjustments in our burden estimate for the information collection. We estimate that 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received through ABI/ACS. We assume the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total annual burden of 2,170,983 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910–0046), as previously discussed.

We estimate that 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. We assume the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

We estimate that 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 cancellations received annually through ABI/ACS. We assume the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 1,760 hours.

We estimate that 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. We assume the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

We estimate that one or fewer requests for review under § 1.283(d) or § 1.285(j) will be submitted annually. We assume that it will take respondents 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we estimate a total reporting burden of 8 hours.

We estimate that 263 post-hold submissions under § 1.285(i) will be submitted annually. We assume that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total reporting burden of 263 hours.

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02371 Filed 2–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3324]

Use of Serological Tests To Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II).'' The guidance document provides blood collection establishments with recommendations regarding the use of